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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/297,652 07/08/99 THOMAS R MIJ-001US

HM22/0824

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EXAMINER

BADIO, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED:

08/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/297,652

Applicant(s)
Thomas

Examiner
Barbara Badio

Group Art Unit
1616



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-37 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-37 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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First Office Action on the Merits

Claim Objections

- W 1. Claims 36 and 37 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claims are method claims but are dependent on composition claims 29 and 35. The claims recite "[a] method according to claim 35(29)" and, thus, do not further limit the parent claims 29 and 35. For the purpose of prior art rejection, it is assumed that the instant claims are composition claims and should read "[a] composition according to claim 35(29)".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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3. Claims 1-5, 7-8, 11-15, 18, 21, 22, 27, and 29-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Papandrea.

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire article; especially page 6, lines 8-14 and page 11, example 2; claims 6-11 and 18). The reference teaches (1) gold compounds such as aurothiomalate, aurothioglucose and auranofin (page 1, Background, lines 1-11; pages 6-8; page 11, example 2); (2) corticosteroid such as betamethasone dipropionate (page 8, lines 5-8; page 11, example 2); and (3) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (page 17, lines 9-16). The composition and method of use taught by the reference are encompassed by the instant claims.

4. Claims 1-5, 7-8, 11-15, 18, 21, 22, 27, and 29-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Papandrea.

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory condition (see the entire article; especially col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims 1-15). The reference teaches (1) gold compounds such as aurothiomalate, aurothioglucose and auranofin (col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example

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2); (2) corticosteroid such as betamethasone dipropionate (col. 3, lines 60-63; col. 5, example 2); and (3) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (col. 8, lines 6-12). The composition and method of use taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papandrea (AU-34351/89 or US 5,527,779).

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory condition (see the entire articles; especially **AU 34351**, page 6, lines 8-14 and page 11, example 2; and **'779**, col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims 1-15). The reference teaches (1) gold compounds such as aurothiomalate, aurothioglucose and auranofin (**AU 34351**, page 1, Background, lines 1-11; pages 6-8; page 11, example 2

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and '779, col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example 2); (2) corticosteroid such as betamethasone dipropionate (**AU 34351**, page 8, lines 5-8; page 11, example 2 and '779, col. 3, lines 60-63; col. 5, example 2); and (3) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (**AU 34351**, page 17, lines 9-16 and '779, col. 8, lines 6-12).

The instant claims (see claims 15, 16, 17, 35 and 36) differ from the references by reciting additional corticosteroids not exemplified by the cited prior art. However, the compounds recited by the instant invention are well known in the art and, thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any corticosteroid, including those of the instant claims, in the composition taught by Papandrea with the reasonable expectation that the composition would be useful as taught by the prior art.

Claim 6 further differs from the references by reciting the administering of at least two corticosteroids.

Claims 10, 16 and 17 further differ from the references by reciting the treatment of rheumatoid arthritis.

Claims 19, 20, 23-25 and 28 further differ from the references by reciting various routes of administration.

However, (1) it is known in the art that corticosteroids and gold compounds are useful in the treatment of rheumatoid arthritis, dermatitis and psoriasis (see for

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example, US patents 3,937,822; 4,119,723 and 4,267,192); (2) it is obvious to combine two or more compounds or compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) and (3) it is within the level of skill of one having ordinary skill in the pharmaceutical art to make various pharmaceutical preparations for administration by different routes. Therefore, the combination of one or two corticosteroids with a gold compound for the treatment of an immune-mediated disorders, such as rheumatoid arthritis, dermatitis and psoriasis, would have been obvious to one having ordinary skill in the art at the time of the invention and the administration of the composition by the recited routes of administration is within the level of skill of the ordinary artisan and, thus, is prima facie obvious.

Telephone Inquiry Contacts

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

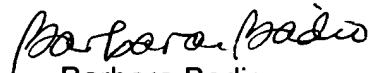
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Barbara Badio
Primary Examiner
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August 23, 2000